IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH and BAYER PHARMA AG,	)	
Plaintiffs,	)	
v.	)	C.A. No. 12-1032-GMS
WARNER CHILCOTT COMPANY, LLC, WARNER CHILCOTT (US), LLC, and WARNER CHILCOTT PLC,	)	
Defendants.	)	

DEFENDANTS' OPENING BRIEF
IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BASED ON
INDEFINITENESS OF US. PATENT NO. 5,980,940

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This is a patent case brought by Plaintiffs Bayer Intellectual Property GMBH and Bayer Pharma AG (collectively, "Bayer") against Defendants Warner Chilcott Company, LLC; Warner Chilcott (US), LLC; and Warner Chilcott plc (collectively, "Warner Chilcott"). Bayer contends that Warner Chilcott's Lo Loestrin oral contraceptive product infringes Bayer's '940 patent,[1] and that Warner Chilcott's '984 patent[2] "interferes" with Bayer's '940 patent. After extensive briefing and argument by the parties, and a *Markman* hearing, the Court held that it could not construe the key disputed limitations of Bayer's '940 patent encompassed in the phrase

> "high contraceptive reliability, low incidence of follicular development, and satisfactory cycle control, with reliable avoidance of intracyclic menstrual bleeding and undesirable side-effects."

As these disputed limitations appear in each and every claim of Bayer's asserted '940 patent, the Court should declare that all claims of the '940 patent are indefinite, and therefore invalid. The Court should further grant summary judgment to Warner Chilcott on Bayer's infringement and interference counts, because a holding that the claims of the '940 patent are indefinite necessarily defeats both counts and disposes of this case in its entirety.

SUMMARY OF ARGUMENT

1. In its claim construction order, the Court held that it was unable to construe the disputed terms "high contraceptive reliability, low incidence of follicular development, and satisfactory cycle control, with reliable avoidance of intracyclic menstrual bleeding and undesirable side-effects." (October 9, 2014 Order Construing The Terms of U.S. Patent No. 5,980,940 (D.I. 120) at 3). That the Court was unable to determine the metes and bounds of these claim terms after reviewing the '940 patent's specification and prosecution history from the

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[1] This brief refers to Bayer's U.S. Patent No. 5,980,940 as "the '940 patent."

[2] This brief refers to Warner Chilcott's U.S. Patent No. 7,704,984 as "the '984 patent." The '984 patent claims the contraceptive method embodied by Lo Loestrin.

standpoint of a person of ordinary skill in the art means that the claims, when "read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention," thereby rendering the claims indefinite under *Nautilus, Inc. v. Biosig. Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014).

2. By definition, an indefinite patent claim cannot be infringed, nor can an indefinite claim interfere with the claims of another patent. Thus, a holding by the Court that the claims of the '940 patent are indefinite defeats Bayer's infringement and interference claims as a matter of law, warranting summary judgment in Warner Chilcott's favor on both counts.

BACKGROUND

A. The Present Action

Bayer's amended complaint asserts two claims: (1) patent infringement and (2) patent interference.

Patent infringement claim. Bayer's infringement claim alleges that Warner Chilcott's sale of the oral contraceptive known as Lo Loestrin infringes the '940 patent. (D.I. 5, Amended Compl. ¶¶ 23-24.) Lo Loestrin administers a sequence of tablets over a 28-day cycle, with one taken per day in the following order:

- 24 combination tablets, each containing 1 milligram of norethindrone acetate (a progestin), and 10 micrograms of ethinyl estradiol (an estrogen);
- 2 estrogen-only tablets, each containing 10 micrograms of ethinyl estradiol; and
- 2 placebo tablets containing no active hormones.

(*Id.* ¶¶ 15-16.) The FDA has only approved Lo Loestrin for administration in the specific order listed above.

The '940 patent claims an oral contraceptive, but that oral contraceptive differs fundamentally from Lo Loestrin. Most notably, in Lo Loestrin, tablets containing only estrogen are provided *before* the inactive placebo tablets, whereas in the ’940 patent, the estrogen-only tablets are taken *after* the inactive placebo tablets. (D.I. 5-1, ’940 patent at col. 7, ll. 10–40; D.I. 5, Amended Compl. ¶¶ 15–16.) Even Bayer has been forced to concede this fundamental difference between Lo Loestrin and the ’940 patent, and has withdrawn its claim of literal infringement accordingly. (D.I. 120, Order at 1.)

Interference claim. Bayer’s second claim is for patent interference under 35 U.S.C. § 291. Two or more patents interfere under 35 U.S.C. § 291 when they claim the same subject matter. *See Albert v. Kevex Corp.*, 729 F.2d 757, 758 n.1 (Fed. Cir. 1984). In the interference claim, Bayer seeks to invalidate Warner Chilcott’s ’984 patent on the theory that the later-issued ’984 patent claims the same subject matter as the earlier-issued ’940 patent. (D.I. 5, Amended Compl. ¶¶ 25–30.)

The Federal Circuit applies a “two-way test” for adjudicating interferences. Under this two-way test, an interference exists only if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party, and *vice versa*—*i.e.*, the patents must invalidate each other in both directions. *See Medichem, S.A. v. Rolabo, S.L.*, 353 F.3d 928, 932 (Fed. Cir. 2003) (describing two-way test for interference-in-fact, which requires a showing that invention A is anticipated or obvious over invention B, and vice versa). Thus, for Bayer to prevail on its interference claim, it bears the burden of proving by clear and convincing evidence that the claims of the ’940 patent would have been anticipated by, or obvious over, the claims of the ’984 patent (if prior art to the ’940 patent), *and* that the claims of the ’984 patent are anticipated by, or obvious over, the claims of the ’940 patent. *See id.*

B. Bayer's '940 Patent

Bayer's '940 patent is directed to a combination oral contraceptive regimen with multiple phases of hormone administration. In the first phase, beginning with the first day of the cycle, a combination of estrogen and progestin is administered daily over 23–24 days, in daily dosage units. '940 patent, col. 3, ll.54–57; col. 1, ll.21–31, col. 5, ll.31–48. After the first phase, 1 or 2 days of blank "placebo" tablets, free of active ingredients, are provided. '940 patent, col. 3, ll.50–54, 57-59; col. 5, ll.35–48; col. 1, ll.21–31. Then, after the administration of "placebo" tablets, there is a second phase of hormone administration, in which estrogen-only tablets are administered daily over 2–4 days. '940 patent, col. 3, ll.59–62; col. 1, ll.21–31; col. 5, ll. 31–48.

The '940 patent contains ten claims. Claim 1 is the only independent claim; the remaining claims depend from claim 1. *Id.* at col. 7–8.

During prosecution, the Examiner initially rejected the claims of the '940 patent as obvious over the prior art. (D.I. 120, Order at 4.) To overcome that rejection, the applicants amended claim 1 to add the "whereby" clause in which the applicants explained that through its "low estrogen content and low total hormone content," the claimed oral contraceptive regimen

> provides high contraceptive reliability, low incidence of follicular development, and satisfactory cycle control, with reliable avoidance of intracyclic menstrual bleeding and undesirable side-effects."

(*Id.*)

The applicants explained that these features distinguished the claimed regimen from prior art oral contraceptives described in the specification of the '940 patent, and that such differences warranted a patent:

> The deficiencies of the prior art multiphasic combination preparations, including those disclosed in Pasquale, are discussed in the specification . . . and contrasted with the superior results of the present regimen, in particular that it provides a contraceptive effect whereby the low effective estrogen content and low total hormone content provides high contraceptive reliability, low incidence of

> follicular development, and satisfactory cycle control, with reliable avoidance of intracyclic menstrual bleeding and undesirable side-effects. . .
>
> There is no teaching in the cited prior art . . . whereby the low effective estrogen content and low total hormone content provides high contraceptive reliability, low incidence of follicular development, and satisfactory cycle control, with reliable avoidance of intracyclic menstrual bleeding and undesirable side-effects. The present invention provided such a low-dose, contraceptively effective pharmaceutical preparation for the first time.

(D.I. 71-8, Exh. 4 at 5.)

After amending the claims to add the whereby clause and explaining that the claimed invention provided an oral contraceptive with "high contraceptive reliability," "low incidence of follicular development," "satisfactory cycle control," and "reliable avoidance of intracyclic menstrual bleeding and undesirable side effects" "for the first time," the inventors obtained the '940 patent on November 9, 1999.

C. Claim Construction Proceedings

The parties presented a number of terms in the claims of the '940 patent for the Court to construe, including the five terms appearing in the phase "high contraceptive reliability, low incidence of follicular development, and satisfactory cycle, with reliable avoidance of intracyclic menstrual bleeding and undesirable side-effects." (D.I. 58-1, Joint Claim Construction Chart at 2–10.) This phrase—and the five terms encompassed in it—appear in claim 1 of the '940 patent. (D.I. 5-1, Amended Compl., Ex A, '940 patent at col. 7, ll. 35–40.) And these terms are incorporated into all of the remaining claims of the '940 patent through dependency. (*Id*. at col. 7, l. 41–col. 8, l. 65.)

Recognizing that these terms by themselves were not adequate to delineate the scope of the claims, each party proposed constructions of such terms. (D.I. 58-1, Joint Claim Construction Chart at 3–10.) Warner Chilcott proposed and "argue[d] that the claimed regimen must be superior to all prior art cited in the patent for every characteristic listed in the disputed phrase."

(D.I. 120, Order at 3.) Bayer, on the other hand, proposed to construe each term "as compared to a population of healthy women not using hormonal birth control." (*Id.* at 7.)

Both parties submitted briefs in support of their proposed constructions, along with intrinsic as well as extrinsic evidence. (D.I. 61-63, 67–71.) The extrinsic evidence included expert declarations from each side. (D.I. 63, 68, 70.) As part of its extrinsic evidence, Bayer submitted a declaration from Dr. Lee Shulman, a medical doctor with "over 25 years of experience as a prescriber of oral contraceptives," who provided "opinions on the proposed claim constructions in this case." (D.I. 68 ¶¶ 1, 8, 10.) For its part, Warner Chilcott submitted declarations from Dr. James Simon, who explained that the disputed limitations in the '940 patent did not have a commonly understood meaning, and that Bayer's proposed constructions did not reflect the understanding of a person of ordinary skill in the art, either. (D.I. 63, 70.) In briefing, Warner Chilcott further explained that Bayer's proposed constructions lacked support in the intrinsic record and were themselves indefinite, and that in the absence of Warner Chilcott's proposed constructions, the disputed claim terms would render the claims of the '940 patent indefinite. (D.I. 62, at 1-2, 10-11, 13, 15, 16; D.I. 69, at 2-11.)

After extensive briefing and a *Markman* hearing, the Court rejected both parties' proposed constructions. (D.I. 120, Order at 3–7.) The Court noted that the disputed phrase includes "subjective words, such as 'high,' 'low,' 'satisfactory,' and 'reliable,' that lack clarity and fail to identify the claim scope." (*Id.* at 3.) After reviewing the patent's specification and prosecution history of the '940 patent from the standpoint of a person of ordinary skill in the art, along with the parties' other evidence and arguments, the Court was unable to identify an objective standard for measuring the degree of these subjective words:

> After rejecting the party's proposals, the court is left at an impasse and is unable to discern the meets and bounds of the asserted claims. The plain meaning of the

> language leaves the court with numerous questions, the answers to which are necessary to complete an infringement analysis regarding when the claim limitations are met. For example, how high must the contraceptive reliability be? What incidence of follicular development would be considered low? What constitutes satisfactory cycle control? And even more problematic are the reliable terms. What level of avoidance is necessary for intracyclic menstrual bleeding, and is it evaluated after the first 28 day administration cycle or after prolonged use? The uncertainty is compounded for side effects. The specification discusses various side effects ranging from headaches to cardiovascular disease. What constitutes an unacceptable avoidance of headaches is a thoroughly different question than what would constitute unacceptable avoidance of cardiovascular disease, yet the two are linked together in a single characteristic in the disputed phrase. Finally, even if the court did have individual standards against which the limitations are measured, the intrinsic record does not indicate what analytical tools or processes should be used to make the measurements.

(*Id.* at 7-8.)

The Court therefore held that the terms in the disputed phrase were not amenable to construction, and observed that "[t]he difficulty the court has encountered in construing the terms may unavoidably present an indefinite issue that will need to be addressed at summary judgment." (*Id.* at 3-8.)

In light of the Court's claim construction order, Warner Chilcott sought permission to suspend expert discovery and file a summary judgment motion seeking a declaration that the claims of the '940 patent are indefinite. In an October 31, 2014 teleconference, the Court granted Warner Chilcott's request. (D.I. 126.) In doing so, the Court denied Bayer's request (D.I. 125, at 2) to adduce further expert opinion on the meaning and scope of the claims of the '940 patent beyond the expert declaration that Bayer had already submitted with its claim construction briefing. (D.I. 68.) The Court stated during the teleconference that it "ha[d] and ha[d] been at liberty to take and consider all kinds of extrinsic evidence"; that the Court had "made it pretty clear in [its] order that in spite of having the benefit of the thoughts of those of skill that [the Court] [was] unable to construe certain of the terms of the patent"; and that the Court therefore "did not see the benefit of further inquiry in the nature of expert opinion." (D.I. 126, 10/31/04 teleconference, at 3.)

Warner Chilcott now submits this motion for summary judgment, seeking a declaration that the claims of the '940 patent are indefinite, and dismissing with prejudice both Bayer's infringement and interference claims.

D. Legal Standards

Summary judgment should be granted where there is no dispute of material fact and the movant is entitled to judgment as a matter of law. *Noah Systems, Inc. v. Intuit, Inc.*, 675 F.3d 1302, 1309–10 (Fed. Cir. 2012). In deciding whether summary judgment is appropriate, a court reviews the evidence in the light most favorable to the non-movant and draws all reasonable inferences in the non-movant's favor. *Augme Technologies, Inc. v. Yahoo! Inc.*, 755 F.3d 1326, 1329 (Fed. Cir. 2014).

Indefiniteness is a question of law. *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1380 (Fed. Cir. 2005). A patent is indefinite if "its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus*, 134 S. Ct. at 2124.

"Indefiniteness is a matter of claim construction, and the same principles that generally govern claim construction are applicable to determining whether allegedly indefinite claim language is subject to construction." *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1319 (Fed. Cir. 2008). Claims that are not amenable to construction are indefinite. *Halliburton Energy Services, Inc. v. M-I LLC*, 514 F.3d 1244, 1250 (Fed. Cir. 2008).

ARGUMENT

I. THE COURT SHOULD GRANT SUMMARY JUDGMENT TO WARNER CHILCOTT ON BAYER'S INFRINGEMENT CLAIM.

A. The claims of the '940 patent are indefinite as a matter of law.

A patent is indefinite "if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus*, 134 S. Ct. at 2124. The Court's recent claim construction order confirms that the claims of the '940 patent are indefinite under this test.

As discussed above, the Court was unable to construe the disputed terms "high contraceptive reliability, low incidence of follicular development, and satisfactory cycle control, with reliable avoidance of intracyclic menstrual bleeding and undesirable side effects." (D.I. 120, Order at 3.) The Court noted that these terms contain "subjective words, such as 'high,' 'low,' 'satisfactory,' and 'reliable,' that lack clarity and fail to identify the claim scope." *Id.* at 3. The Court also found that nothing in the specification or the prosecution history provided a person of ordinary skill in the art with an objective standard to measure the scope of these subjective words. *See supra* pp. 6-7. For that reason, after rejecting the parties' proposed constructions of these terms, the Court was "left at an impasse and [was] unable to discern the meets and bounds of the asserted claims." (D.I. 120, Order at 7.)

That the Court could not determine the metes and bounds of this language, or arrive at a construction of these claim terms after reviewing the specification and prosecution history of the '940 patent from the perspective of a person of ordinary skill in the art, means that the claims, when "read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus*, 134 S. Ct. at 2124. Claims that are not amenable to construction are indefinite, *see*

Halliburton Energy Services, Inc. v. M-I LLC, 514 F.3d 1244, 1250 (Fed. Cir. 2008), and courts repeatedly have held claims indefinite as a matter of law when they have been unable to discern the scope of the claims at the *Markman* stage.[3]

Summary judgment of indefiniteness is further supported by the Federal Circuit's recent decision in *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364 (Fed. Cir. 2014). There, the Federal Circuit upheld a holding of indefiniteness after the district court ruled at *Markman* that the term "unobtrusive manner" rendered several claims indefinite. *Interval Licensing*, 766 F.3d at 1366. The Federal Circuit observed that, on its face, the disputed term was "highly subjective," and that the claims incorporating this term were indefinite because nothing in the specification or prosecution history provided an objective standard for measuring the scope of that phrase. *Id.* at 1371–73. The Federal Circuit held that the challenged claim language was indefinite, based on the text of the claim, the specification, and the prosecution history. *Id.* at 1370 n.6, 1374.

Just as in *Interval Licensing*, the claims of the '940 patent here contain "subjective" words that lack clarity and fail to identify claim scope. (D.I. 120, Order at 3.) And, just as in *Interval Licensing*, this Court has found that neither the specification nor the prosecution history provides an objective standard that would enable a person of ordinary skill in the art to discern the scope of the claims. (*Id.* at 3, 7.) Consistent with *Interval Licensing*, this Court should grant summary judgment to Warner Chilcott, declaring that the claims of the '940 patent are indefinite and invalid because the claim language, specification, and the prosecution history do not inform with reasonable certainty a person of ordinary skill in the art as to the scope of several subjective terms that are incorporated into all of the claims of the '940 patent.

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[3] *Interval Licensing LLC v. AOL Inc.*, 766 F.3d 1364 (Fed. Cir. 2014) (affirming district court's holding at *Markman*/claim construction phase that claim was indefinite); *Triton Tech of Texas, LLC v. Nintendo of America, Inc.*, 753 F.3d 1375 (Fed. Cir. 2014) (same); *Function Media, L.L.C. v. Google, Inc.*, 708 F.3d 1310 (Fed. Cir. 2013) (same); *Noah Systems, Inc. v. Intuit, Inc.*, 675 F.3d 1302 (Fed. Cir. 2012) (affirming district court's holding at *Markman*/claim construction phase that claim was indefinite and therefore that summary judgment was proper); *Halliburton Energy Services, Inc. v. M-I LLC*, 514 F.3d 1244 (Fed. Cir. 2008) (same); *Southwestern Bell Telephone Co. v. Arthur A. Collins, Inc.*, 279 Fed. Appx. 989 (Fed. Cir. 2008) (affirming district court's holding at *Markman*/claim construction phase that claim could not be construed and was therefore indefinite); *Microstrategy Inc. v. Business Objects Americas*, 410 F. Supp. 2d 348 (D. Del. 2006) (holding claims indefinite at claim construction and accordingly granting summary judgment of indefiniteness), *aff'd by Microstrategy Inc. v. Business Objects Americas*, 238 Fed. Appx. 605 (Fed. Cir. 2007).

B. Further expert discovery is inappropriate and could not change the fact that the claims are indefinite.

Bayer has indicated that it will oppose summary judgment on the ground that additional expert analysis is necessary regarding the understanding of a person of ordinary skill in the art, and that further expert opinion is therefore needed to resolve Warner Chilcott's motion. But in construing the claims, the Court has *already* considered the meaning of the claim terms from the standpoint of a person of ordinary skill in the art, as *Phillips v. AWH Corp.* requires, and as the parties noted in briefing. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) ("It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. . . .[that person] is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification. . . Thus, the court starts the decisionmaking process by reviewing the same resources as would that person, *viz.*, the patent specification and the prosecution history."); *see also* D.I. 62, Warner Chilcott's Claim Construction Opening Brief at 3 (noting that, for purposes of claim construction, the "claims are construed through the eyes of the 'person of ordinary skill' in the art (POSA) at the time of the invention"); D.I. 67, Bayer's Claim Construction Answering Brief at 1 n.1 ("Bayer does not dispute Warner Chilcott's definition of the person of ordinary skill in the art for purposes of claim construction."). Thus, the Court has *already done* what the Court must do for purposes of an indefiniteness analysis—evaluate the claims of the ’940 patent, in light of the specification and prosecution history, from the standpoint of a person of ordinary skill in the art, to determine the claims’ meaning and scope.

Further, Bayer *already* submitted an expert declaration in support of its contention that a person of ordinary skill in the art would have concluded that each disputed term should be construed “as compared to a population of healthy women not using hormonal birth control.” (*See* D.I. 68, Declaration of Lee P. Shulman, M.D. in Support of Plaintiffs’ Claim Construction Answering Brief.) But, after considering Bayer’s submission, including the declaration from Dr. Shulman, the Court nevertheless *rejected* Bayer’s proposed construction, as well as “Bayer’s argument that each term within the disputed phrase has a known meaning in the art that supports comparisons to ‘a population of healthy women not using hormonal birth control.’” (D.I. 120, Order at 7.)

The Court has therefore issued its claim construction ruling, and further expert opinion would not improve the Court’s ability to construe the claims, as the Court itself noted during the October 31, 2014 teleconference. (D.I. 126, 10/31/2014 teleconference, at 3) (“I have . . . consider[ed] all kinds of extrinsic evidence. . . I think I have made it pretty clear in my order that in spite of having the benefit of the thoughts of those of skill that I have been unable to construe certain of the terms in the patent. I really don’t see the benefit of further inquiry in the nature of expert opinion.”)

Nor could additional expert testimony change the Court’s analysis, or the fact that the claims of the ’940 patent, when read in light of the benchmark-free specification and prosecution history, fail to inform with reasonable certainty, those of skill in the art, about the scope of the claims of the ’940 patent. *See, e.g.*, *Interval Licensing*, 766 F.3d at 1370 n.6, 1371-74.

Any argument from Bayer about the need for additional expert submissions is simply an attempt to get a second bite at the apple on an issue that has already been resolved. If Bayer believed that additional expert opinion would be helpful to the Court in construing the claims, Bayer should have submitted that additional opinion in the claim construction process, not *months after* the Court had issued its claim construction order.

C. Because the claims of the ’940 patent are indefinite, Bayer’s infringement claim should be dismissed with prejudice.

The Court should dismiss Bayer’s infringement claim with prejudice because indefinite claims are invalid, and invalidity is a complete defense to infringement. *See, e.g.*, *Tate Access Floors, Inc. v. Interface Architectural Resources, Inc.*, 279 F.3d 1357, 1369 (Fed. Cir. 2002) (“Of course . . . invalidity is a defense to an action for patent infringement.”).

Furthermore, it is impossible for Bayer to prove infringement. To determine whether a claim is infringed, a court must first construe the claim, and then compare the construed claim to the allegedly infringing product. *Honeywell International, Inc. v. International Trade Commission*, 341 F.3d 1332, 1342 (Fed. Cir. 2003); *Nazomi Communications, Inc. v. Arm Holdings PLC*, 403 F.3d 1364, 1367–68 (Fed. Cir. 2005) (“Infringement is a two-step inquiry, in which a court must first construe disputed claim terms, and then compare the properly construed claims to the accused device.”); *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1337 (Fed. Cir. 2005). But “[i]f a claim is indefinite, the claim, by definition, cannot be construed.” *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1332 (Fed. Cir. 2010). It is thus impossible for an indefinite claim to be infringed, because a court cannot move past the first step of the required two-step infringement analysis. *Honeywell International*, 341 F.3d at 1342; *Viskase Corp. v. American National Can Co.*, 261 F.3d 1316, 1323 (Fed. Cir. 2001) (“an invalid claim cannot be infringed”). Put simply, Bayer cannot meet its burden of proving that Lo

Loestrin infringes the asserted claims because the scope of those claims cannot be determined, and also because the claims are invalid.

II. THE COURT SHOULD ALSO GRANT WARNER CHILCOTT SUMMARY JUDGMENT ON BAYER'S INTERFERENCE CLAIM.

As noted above, Bayer also asserts a count for patent interference under 35 U.S.C. § 291. *See supra* p. 3. Bayer's interference count alleges that the '984 patent claims the same subject matter as the '940 patent, and that the '984 patent should therefore be held invalid. However, because the claims of the '940 patent are indefinite, Bayer's contention that the '940 and '984 patents interfere must also fail as a matter of law.

For Bayer to establish an interference-in-fact, it must prove that the subject matter of the claims of the '984 patent, considered as prior art to the '940 patent, anticipates or renders obvious the claims of the '940 patent—and vice versa. *See Medichem, S.A. v. Rolabo, S.L.*, 353 F.3d 928, 932 (Fed. Cir. 2003) (describing two-way test for interference-in-fact, which requires a showing that invention A is anticipated or obvious over invention B, and vice versa). Bayer bears the burden of establishing an interference-in-fact by clear and convincing evidence. *See Genetics Institute, LLC v. Novartis Vaccines and Diagnostics, Inc.*, 687 F. Supp. 2d 486, 496 (D. Del. 2010) (requiring showing of clear and convincing evidence with respect to obviousness prong of two-way test), *aff'd*, 655 F.3d 1291 (Fed. Cir. 2011).

But the anticipation and obviousness analyses that make up the two-way test require that the claims be properly construed before the court can conduct the requisite comparison to the prior art. *See Medichem*, 353 F.3d at 933 ("The first step in both [the anticipation and obviousness] analyses is a proper construction of the claims"). An indefinite claim, however, is one that "by definition, cannot be construed." *Enzo Biochem*, 599 F.3d at 1332. Such claims therefore cannot be anticipated or obvious. *See In re Aoyama*, 656 F.3d 1293, 1298 (Fed. Cir.

2011) ("[B]ecause 'a claim cannot be both indefinite and anticipated,' this court does not reach the ground relied on by the Board [regarding anticipation of claims].") (internal citations omitted); *Enzo Biochem*, 599 F.3d at 1332 (Fed. Cir. 2010) ("Without a discernible claim construction, an anticipation analysis cannot be performed."). *See also Blackberry Corp. v. Mobilemedia Ideas, LLC*, Paper 65, Case No. IPR2013-00036, 20 (P.T.A.B. March 7, 2014)[4] (suspending *inter partes* review proceedings where the claims at issue were indefinite, on the ground that it could not therefore "ascertain[] differences between the claimed subject matter and the prior art" needed to conduct an obviousness analysis).

As a matter of law, then, Bayer cannot meet the requirements of the two-way test with respect to indefinite claims, and the '940 and '984 patents cannot be found to interfere. A finding of indefiniteness therefore deprives this Court of jurisdiction over Bayer's § 291 claim. *Albert v. Kevex Corp.*, 729 F.2d 757, 760-61 (Fed. Cir. 1984) ("We hold that the court has no jurisdiction under § 291 unless interference is established."). The Court should therefore grant summary judgment of no interference-in-fact and dismiss Bayer's interference claim. Alternatively, summary judgment is appropriate because, by virtue of the claims of the '940 patent being indefinite, Bayer cannot show that the claims of that patent would have been anticipated by, or obvious over, the claims of the '984 patent, thus defeating its interference contention as a matter of law.

Bayer's interference claim should also be dismissed because an interference claim cannot be sustained when the underlying patent cannot support an infringement suit and lacks residual value. *See, e.g., Bally Gaming, Inc. v. Kappos*, 888 F. Supp. 2d 108, 112 (D.D.C. 2011)

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[4] Pursuant to Local Rule 7.1.3(a)(7), Warner Chilcott has attached this opinion to this brief as Exhibit 1 because that decision is not available on Westlaw or Lexis.

(dismissing interference claim where the allegedly interfering patent had been expired for over ten years, and had no remaining value) ("While dicta in the [*Genetics*] opinion refers in fairly broad generalities to 'expired patents' as a category, the court's decision turned on the value and import of the patent in question."). Here, the fact that the '940 patent claims are indefinite and therefore invalid means that they cannot sustain an infringement claim and lack any residual value. In addition, that the claims of the '940 patent are indefinite and invalid also deprives Bayer of Article III standing to assert the interference claim, because under such circumstances, the interference claim could not redress any "real and immediate" injury to Bayer. *See, e.g.*, *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (dispute must be "real" and "immediate" for plaintiff to maintain suit under Article III's standing requirement).

CONCLUSION

For the reasons discussed above, this Court should enter an order declaring that the claims of the '940 patent are indefinite, dismiss with prejudice Bayer's infringement and interference counts, and grant judgment as a matter of law to Warner Chilcott on those claims.

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